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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,329	04/11/2002	Toshio Kitamura	06501-095001	7008
7590	03/09/2004			
Fish & Richardson 225 Franklin Street Boston, MA 02110-2804			EXAMINER HILL, MYRON G	
			ART UNIT	PAPER NUMBER

1648

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,329

Applicant(s)

KITAMURA ET AL.

Examiner

Myron G. Hill

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1- 15 is/are pending in the application.
- 4a) Of the above claim(s) 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1- 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/25/02, 4/11/03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claim 15 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election of Group I was made **without** traverse in paper filed 12/22/2003.

This action is on claims 1- 14.

Information Disclosure Statement

Signed and initialed copies of the IDSs filed 6/25/02 and 4/11/03 are enclosed.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See at least page 15, line 30.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 refers to a cell. It is not clear that this is an

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isolated cell. It suggested that the term be amended to recite "isolated cell" to avoid reading on a product of nature. In claim 7, it is not clear what is meant by "bound". The specification indicates that the DNA sequence comprises DNA encoding retroviral structural gene(s) and sequences encoding a marker not some sort of hybrid. It is not clear in claims 9 and 10 what the cells are after they have been "derived" from the recited cells. The metes and bounds of "derived" is not clear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is not enabling for the said claims. The specification does not provide a repeatable method for obtaining a cell used for the production of retroviruses, and it does not appear to be readily available material. Deposit of the cells would satisfy the enablement requirements of 35 U.S.C. 112. Applicant's deposit statement on specification page 13, does not indicate the extent of public availability.

If a deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his or her signature, stating that the deposit has been made under the terms of the Budapest Treaty and that **all restrictions imposed by the depositor on the availability to the**

public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 CFR 1.808.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klatzmann *et al.* (WO 98/02529) (an English language equivalent is used, US 2002/0123146 A1) and Hobbs *et al.*

Klatzmann *et al.* teach the invention essentially as claimed. Klatzmann *et al.* teaches a cell used for the production of retroviruses that comprise a DNA sequence encoding retroviral structural proteins (RSP) operably linked downstream of a promoter (paragraph 0054), the RSP are contained on one or two constructs expressing them (FIG. 1b), and the construct contains an IRES and selectable marker (paragraph 0047). Also, Klatzmann *et al.* teach a method of producing a retrovirus comprising introducing a retroviral vector which lacks at least one or all viral structural proteins and includes a foreign gene (paragraph 0063) into a packaging cell which contains a DNA sequence encoding retroviral structural proteins (RSP) operably linked downstream of a promoter (paragraph 0054, and claims 4 and 11).

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Klatzmann *et al.* do not teach the use of an EF1alpha promoter in the packaging constructs or 293T cells.

Hobbs *et al.* teach a strong promoter that leads to high levels of recombinant proteins being expressed (abstract). This is the EF1 alpha promoter. Also, Hobbs *et al.* teach that this promoter routinely achieved high levels of expression in 293T cells (page 368 column 2, last paragraph).

One of ordinary skill in the art at the time of invention would have been motivated to use the promoter of Hobbs *et al.* because Klatzmann *et al.* teach that any strong promoter can be used and it is the aim to produce large amounts of *gag* and *pol* in order to obtain high titers of transgene virus (paragraphs 0041 and 0054). One of skill in the art at the time of invention would know different tropisms of retroviruses and that the *gag* and *pol* play a roll in this. Klatzmann *et al.* teach tropism and that the choice of envelope depend on the receptor/cell that is the target (paragraph 0054). 293 cells are well known in the art and are known to be transfectable and useful in propagating/ growing virus. Hobbs *et al.* teach that 293T cells were good hosts for protein production.

Claim 9 is included in this rejection because even though there is a deposit, the product is unpatentable for reasons explained in this rejection.

Thus, it would be *prima facie* obvious to one of ordinary skill in the art at the time of invention to modify the packaging cell of Klatzmann *et al.* with the promoter of Hobbs *et al.* with the expectation of success because the promoter is shown to be strong and meets the requirements of Klatzmann *et al.*

Therefore, the invention is unpatentable over Klatzmann *et al.* and Hobbs *et al.*


Conclusion


No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Myron G. Hill
Patent Examiner
March 8, 2004


JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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3/8/04